



PESTICIDE FACT SHEET

Name of Chemical(s): Fish oil
Reason for Issuance: Unconditional registration
Date Issued: February, 1998
Fact Sheet Number:

1. DESCRIPTION OF THE CHEMICAL(S)

Generic Name(s) of the
Active Ingredient(s): Fish oil

OPP Chemical Code: 122401
Year of Initial Registration: 1998
Trade name of end-use product: Game Stop
Type of Pesticide: Repellant
Basic Producers: AL'Tech.
Boyeres
37340 Ambillou
France

U.S. Agent: Landis International Inc.
P.O.Box 5209
Valdosta, GA 31603-5209

2. USE SITES, APPLICATION TIMING & TARGET PESTS

Target Pests: *Rabbits and deer.*

Registered Uses: There is no registered technical, the end-use product Game Stop is produced by a non-integrated process, i.e. the final product is produced in a single step by addition of water. The end-use involves application to foliage and twigs

of trees shrubs and ornamental plants which are fed upon by rabbits and deer. Formulated product will be applied by direct and broadcast spray . treatments.

Application Timing: As needed. Repeat at 2-4 weeks interval.

3. FOOD CLEARANCES / TOLERANCES

A numeric tolerance or exemption from the requirement of a tolerance is not needed since there are no food uses associated with the registration. Safety factors from the Food Quality Protection Act of 1996 (FQPA) were considered.

4. SCIENCE FINDINGS

A. CHEMICAL DESCRIPTION

The active ingredient, fish oil is a naturally occurring active ingredient (a.i). The end use product is not manufactured by an integrated process. It is a liquid formulation containing 11.6% a.i. and 88.4% inert ingredients. The CAS number for fish oil is 8002-50-4.

B. BIOCHEMICAL CLASSIFICATION

Fish oil is a naturally occurring substance extracted from edible fish. It is a biochemical and therefore, for regulatory purposes it is subject to a reduced set of data requirements.

C. TOXICOLOGY:

The following toxicity studies were submitted and reviews were found acceptable using a technical grade manufacturing product:

1. Guideline No. 152-10 Acute Oral Toxicity in Rats: Toxicity Category III.
2. Guideline No. 152-11 Acute Dermal Toxicity in Rabbits: Toxicity Category III.
3. Guideline No. 152-12 Acute Inhalation Toxicity in Rats: Waived
4. Guideline No. 152-13 Primary Eye Irritation in Rabbits: Toxicity Category III.
5. Guideline No. 152-14 Primary Dermal Irritation in Rabbits: Toxicity category IV.

The acute inhalation study was waived based on low toxicity and low application rates. A 90-day feeding study was not required because the non-food uses do not require a tolerance or an exemption from the requirement of a tolerance; and proposed uses are not likely to result in

repeated human exposure by the oral route. The triggers for genotoxicity studies were not met and thus the studies are not required.

D. FOOD QUALITY PROTECTION ACT REQUIREMENTS

Safety factors from FQPA were evaluated. BPPD has considered, among other factors, available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. Given the low toxicity of fish oil as indicated by toxicity data, and a history of safe use in other parts of the world, a determination of reasonable certainty of no harm for the general population, as well as subgroups including infants and children, was made.

E. HUMAN HEALTH EFFECTS

1. Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

There are no food uses associated with the registration of Game Stop containing the active ingredient fish oil. Therefore, acute and chronic dietary risks should be minimal based on lack of exposure. Furthermore, results from mammalian acute and subchronic toxicity studies indicate lack of toxicity, adding further weight to the lack of risk from exposure. Therefore, the Agency concludes that there is a reasonable certainty of no harm from dietary exposure to sensitive Subpopulations including infants and children.

2. Common Mode of Action

Fish oil shares a common metabolic mechanism with other edible fats and oils, however, these other fats and oils are not expected to pose significant contributions to the cumulative effects from the use of Game Stop.

3. Risks Posed by Potential Residential, School or Day Care Exposure

No indoor residential, school or day care uses currently appear on the label. The proposed use pattern is for ornamental and non-ornamental plants (non-food use only). There is a potential for dermal exposure at these sites where children are present but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted toxicological studies and the relatively low application rate.

4. Drinking Water Exposure and Risk Characterization

No significant exposure is expected to result from fish oil because it is likely to be biodegraded in the terrestrial and aquatic environments. Health risk to humans is considered negligible based on low toxicity and low application rate of the active ingredient.

5. Aggregate Exposure

The Agency has considered the various routes of exposure (dietary, drinking water, and exposure from non-occupational sources) and potential risks of the subject compound and determined that the proposed use of the active ingredient does not pose significant risk over a lifetime to populations including infants and children. This is demonstrated by low acute mammalian toxicity, and a history of safe use of the compound in other countries.

F. OCCUPATIONAL AND RESIDENTIAL EXPOSURE AND RISK CHARACTERIZATION:

Because of the lack of significant mammalian acute toxicity, low application rates, and a lack of reports of toxicity or allergic reactions from use in other parts of the world, occupational exposure data are not required at this time. Risks from occupational exposure will be mitigated through appropriate precautionary labeling.

G. ENVIRONMENTAL ASSESSMENT

The ecological data requirements studies are waived for fish oil based on information from the public literature submitted by the registrant, low acute toxicity, low application rate and natural occurrence. The label language is proposed to prevent direct application to water.

H. ECOLOGICAL EFFECTS:

All of the Tier I ecological effects data requirement studies are waived based on reasons provided above under Environmental Assessment.

I. ENVIRONMENTAL FATE AND GROUND WATER DATA

The environmental fate data requirements were not triggered because no human health or ecological effects issues were manifested. The need for environmental fate and groundwater data was not triggered under current requirements (40CFR section 158.690(d)(2)(vii through xv). Since Tier II studies were not triggered, there is no requirement for environmental fate data.

J. ECOLOGICAL RISK ASSESSMENT

The Agency has no information about direct exposure to nontarget insects, fish, and other wildlife. A potential for exposure exists to nontarget insects, fish and other wildlife with foliar spray applications.. However, the non-target requirements are waived since Game Stop is practically nontoxic to birds, freshwater fish, and aquatic invertebrates. Low toxicity, the proposed rate of application, and mitigating label language present minimal to nonexistent risk to wildlife.

REQUIRED ENVIRONMENTAL HAZARDS STATEMENT ON THE END-USE PRODUCT LABEL

“Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in

neighboring areas. Do not contaminate water when disposing of rinsate or equipment washwaters.”

5. SUMMARY OF REQUIRED DATA : All hypersensitivity incidents must be reported to the Agency when/if they occur.

6. REGULATORY ACTIONS Unacceptable adverse effects from the use of Game Stop are not expected. Unconditional registration was issued.

7. CONTACT PERSON AT EPA

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